UNPUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

NANCY L. RULE,
Plaintiff-Appellant,

v.

BEST INDUSTRIES, INCORPORATED,

No. 96-1624

Defendant-Appellee,

and

ROANOKE MEMORIAL HOSPITAL,
Defendant.

Appeal from the United States District Court
for the Western District of Virginia, at Roanoke.
James C. Turk, District Judge.
(CA-92-73-R)

Argued: January 31, 1997

Decided: August 25, 1997

Before HALL and ERVIN, Circuit Judges, and
CLARKE, Senior United States District Judge for the
Eastern District of Virginia, sitting by designation.

Affirmed by unpublished per curiam opinion. Judge Ervin wrote a
dissenting opinion.

COUNSEL

ARGUED: David Burton, BURTON & KILGORE, Princeton, West
Virginia, for Appellant. Jeffery Scott Sexton, GENTRY, LOCKE,

RAKES & MOORE, Roanoke, Virginia, for Appellee. **ON BRIEF:** Debra Kilgore, BURTON & KILGORE, Princeton, West Virginia; Mark S. Hicks, Dublin, Virginia, for Appellant. Leisa Kube Ciaffone, GENTRY, LOCKE, RAKES & MOORE, Roanoke, Virginia, for Appellee.

OPINION

PER CURIAM:

Nancy Rule appeals an order of the district court granting summary judgment to the defendant in Rule's product liability suit. We affirm.

I.

In the fall of 1989, plaintiff Nancy Rule was diagnosed with squamous cell carcinoma of the cervix. She was referred to the Cancer Center of Southwest Virginia in Roanoke for radiation therapy. Dr. Robert Heath was her lead physician there.

After 25 sessions of external radiation, Dr. Heath decided to use a "cesium implant" in the uterus to apply radiation internally. Two attempts to place the implant using a "tandem" were unsuccessful.

Dr. Heath, along with Drs. Patton Saul and Thomas Stoecker, then decided to use a device Dr. Heath had learned about at the University of North Carolina, a type of thin catheter called a"Flexineedle." Defendant Best Industries, Inc., manufactures the Flexineedle that Dr. Heath ordered. The hospital's physicist, Joseph Surace, procured the Flexineedle from Best.

A Flexineedle has a needle-like metal core (called the obturator) surrounded by a thin plastic catheter. The purpose of the obturator is

to make the Flexineedle rigid during placement. Once the catheter is in place -- a fact usually verified by ultrasonography -- the obturator is withdrawn and the catheter is filled with the prescribed medication. It can then be left inside the patient for several weeks.

The procedure was performed on January 29, 1990, by Dr. Heath with the assistance of Drs. Stoecker and Saul. None of the doctors read the instructions or warnings that Best enclosed with the Flexineedle. Rule is obese, and Dr. Heath had trouble seeing the Flexineedle on the ultrasound machine. The doctors decided to remove the obturator and fill the catheter with saline. They hoped that this stratagem would allow them to see the catheter and to wiggle and jiggle it into place.

These things were done, and, unknown to the doctors, they had manipulated the catheter into a curved position. Rather than withdraw the catheter and start over, Dr. Heath reinserted the obturator. When the metal needle encountered the curved inner surface of the fragile catheter, it simply sawed the catheter off. Nine and one-half centimeters of the tubing were lost inside Rule's abdomen. The doctors were unable to find it.

The wayward catheter soon caused Rule great abdominal discomfort. She eventually had to have a radical hysterectomy and resections of her urinary tract. During this surgery, the catheter was found in her bladder. She has since lost her right kidney.

Under Virginia law, claims of medical malpractice may be referred to an administrative "medical review panel" by the accused health care provider, and, if so referred, they are not cognizable in court until the review concludes. Va. Code § 8.01 581.2. Rule's claims against the doctors went this administrative route. However, out of fear that the statute of limitations on any claims against Best or the hospital might run while the medical review panel deliberated, she filed a separate action against them in district court. Jurisdiction was based on diversity of citizenship. The hospital moved to dismiss the claims against it, arguing that they, too, were subject to the state administrative review procedure. The district court agreed and granted the hospital's motion.

After discovery, Best moved for summary judgment. The district court initially denied the motion, but granted it on Best's motion for reconsideration.**1**

Rule appeals.

II.

The substantive law of Virginia applies in this diversity case. We review a summary judgment de novo; consequently, we apply the same standard as did the district court -- whether the plaintiff has presented sufficient evidence that a reasonable trier of fact could return a verdict for her. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). The plaintiff's evidence must be assumed to be true, and any disputed issues resolved in her favor, but it must nonetheless be of such quantity and character that crediting it would be rational. See Sylvia Development Corp. v. Calvert County, 48 F.3d 810, 817-818 (4th Cir. 1995).

Rule's theory is not that the Flexineedle was itself defective in either design or manufacture. Instead, she asserts that the actions of the doctors were a foreseeable and dangerous misuse of the product, and Best therefore had a duty to warn against such misuse. See Logan v. Montgomery Ward & Co., 216 Va. 425, 219 S.E.2d 685, 687 (1975).

This theory faces several hurdles. First of all, several experts testified, and none said otherwise, that reinsertion of the obturator into a fragile catheter is more or less absurd. For example, Dr. Margaret Barnes, who was an expert retained by Rule to testify against the doctors, stated, "I believe that it is not unreasonable to expect any modern-day physician who has ever started an IV to be familiar with that risk [breaking the catheter with a needle]." Because Best sold the Flexineedles only to medical professionals --"learned intermedi-

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1 While this suit was pending below, the medical review panel completed its work, and Rule filed a separate suit against the doctors and hospital. She moved to consolidate the cases; the district court denied the motion. She challenges this ruling on appeal, but, because we affirm the summary judgment for Best, the issue is moot.

aries" -- it is entitled to assume that these professionals have a certain modicum of basic medical knowledge. See Pfizer, Inc. v. Jones, 221 Va. 681, 272 S.E.2d 43, 44-45 (1980).

No one, not even plaintiff's expert Dr. Mahesh Varia,**2** testified that removing the obturator and then reinserting it is acceptable medical practice. Rule points to portions of Dr. Varia's testimony in which he calls Dr. Heath's use of the product "reasonable," but it is quite clear from the rest of his testimony that he meant only that it is reasonable to use the Flexineedle in a deep body cavity. Indeed, on cross-examination, Varia was asked whether it would be a deviation from the standard of care to remove the obturator from the Flexineedle before it was properly placed, to which he replied,"Yes, I think that you want to leave the [obturator] in until you position the catheter." In a later affidavit, Dr. Varia stated, among other things:

> It is common knowledge among medical professionals using Flexineedles or similar catheters that withdrawal of an obturator and reinsertion while the Flexineedle is in body tissue could potentially cause the Flexineedles to crack or break.

The only other evidence arguably in Rule's favor is the testimony of the doctors who performed the procedure and Surace (who is not a physician) to the effect that they were "surprised" that the needle broke. But Rule admitted in interrogatories that these physicians acted negligently; she cannot simultaneously rely on their negligent "surprise" to posit that the product was being reasonably used.

The second problem with Rule's failure-to-warn theory is its very premise. Though there is no specific "warning" about removing and reinserting the obturator while the device is inside the body,**3** the Flexineedle's instructions state that "obturators are left in place until the time each is afterloaded with the appropriate radioactive source."

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2 Dr. Varia is Associate Chairman of the Department of Radiation Oncology at the University of North Carolina at Chapel Hill.
3 There is a warning that the needle tips can break if they encounter bone or other hard tissue, which would, at the very least, call any physician's attention to their fragility.

Thus, though there is no warning against the particular misuse here, there is a clear instruction of proper use that, if followed, would eliminate the possibility of such misuse. We believe that, especially inasmuch as the user is a professional, this "warning" is sufficient.

Finally, as the district court noted, Dr. Heath did not even read the materials provided by Best. He had used the Flexineedles before and had observed their use by others. He was confident that he knew what he was doing. It would not have mattered what Best's warnings said, and the alleged lack of warning was not a proximate cause of Rule's injury.**4**

The judgment of the district court is affirmed.

AFFIRMED

ERVIN, Circuit Judge, dissenting:

Because I believe the majority misconstrues the nature of Nancy Rule's complaint and otherwise misapplies the standards for granting summary judgment, I respectfully dissent.

I.

Virginia products liability law is not extensively developed, but its general precepts are relatively clear. A manufacturer is not an insurer of its product's safety. Owens-Corning Fiberglas Corp. v. Watson, 413 S.E.2d 630, 634 (Va. 1992). It therefore need not supply an accident-proof product. Turner v. Manning, Maxwell & Moore, Inc., 217 S.E.2d 863, 868 (Va. 1975). When a cause of action depends upon a defect in the product, the manufacturer must satisfy essentially the same standard of safety whether the theory of liability be labeled

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4 Rule does attempt to lay part of the blame for the doctors' failure to read Best's Flexineedle literature at Best's doorstep. Her expert witness, W. Patrick McVay, opined that it is "conceivable" for Best to provide the Flexineedle instructions and warnings in a "breather bag" that could be available in the operating room should a physician desire to consult them. This opinion is precisely the sort of conjecture that we held insufficient to prevent summary judgment in Sylvia Development Corp.

warranty or negligence. Logan v. Montgomery Ward & Co., 219 S.E.2d 685, 687 (Va. 1975).

> The product must be fit for the ordinary purposes for which it is to be used. . . . Under either the warranty theory or the negligence theory the plaintiff must show, (1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands.

Id. (citations omitted).

A cause of action may also be predicated upon a failure to warn or inadequate warnings. However, a manufacturer possesses a duty to warn only if it knows or has reason to know--but not "should know" --that its product is dangerous. Watson, 413 S.E.2d at 634-35. Liability will be extended to the manufacturer in these circumstances if it

> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
>
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Featherall v. Firestone Tire and Rubber Co., 252 S.E.2d 358, 366 (Va. 1979) (quoting and adopting Restatement (Second) of Torts § 388). There is no duty to warn "when the product is used in an unlikely, unexpected or unforeseeable manner." Id. at 367 (internal quotation marks and citation omitted); see also Layne-Atlantic Co. v. Koppers Co., 201 S.E.2d 609, 614 (Va. 1974).

A.

Although the majority contends that Rule only alleges a cause of action for breach of the duty to warn, and not for a defective product,

see slip op. at 4, Rule's complaint plainly states a cause of action under a defective product theory, see J.A. at 6, and the district court expressly stated that she was proceeding on both theories, see J.A. at 27. I consider first, then, Rule's claim that the Flexineedle was defective.

Although there is little Virginia case law to support it, we have previously stated:

> In determining what constitutes an unreasonably dangerous defect, a court will consider safety standards promulgated by the government or the relevant industry, as well as the reasonable expectations of consumers. Consumer expectations, which may differ from government or industry standards, can be established through evidence of actual industry practice, . . . published literature, and from direct evidence of what reasonable purchasers considered defective.

Alevromagiros v. Hechinger Co., 993 F.2d 417, 420-21 (4th Cir. 1993) (internal quotation marks omitted) (citing and quoting Sexton v. Bell Helmets, Inc., 926 F.2d 331, 337 (4th Cir.) (applying Kentucky law), cert. denied, 502 U.S. 820 (1991)). The district court relied upon this formulation in determining that Rule had failed to rebut Best's affidavits establishing that reasonable physicians, the appropriate consumer group in this case, would not have expected that the obturator could be reinserted into the catheter while the catheter remained in the body. See J.A. at 31-34.

In particular, Best points to the deposition testimony or affidavits of a number of medical specialists. Dr. Margaret Barnes, a radiation oncologist and expert for Rule, stated:

> You really should never pull the plastic catheter back against the metal trochar, whether it's a sharp needle or a blunt metal trochar because shearing can occur.
>
> And I believe that it is not unreasonable to expect any modern day physician who [has] ever started an IV to be familiar with that risk.

J.A. at 199. Dr. Mahesh Varia, a radiation oncologist who testified on Heath's behalf at the medical review board hearing, later stated in an affidavit on behalf of Best:

> It is common knowledge among medical professionals using Flexineedles or similar catheters that withdrawal of an obturator and reinsertion while the Flexineedle is in body tissue could potentially cause the Flexineedle[ ] to crack or break.

J.A. at 397. Best also presented the affidavits of two other radiation oncologists, Dr. Dattatreyudu Nori and Dr. Silvio Aristizabal, to similar effect. See J.A. at 402, 407.

The district court found these statements dispositive: "Rule has not come forward with any expert testimony to counteract Best's evidence." J.A. at 33. The majority agrees, although somehow in the context of Rule's duty to warn theory. See slip op. at 4-5. However, the district court, and apparently the majority as well, has misconstrued the burden placed on Rule to oppose Best's motion for summary judgment and improperly rejected or ignored her countervailing evidence. Since Best relied upon supporting affidavits in its Rule 56(c) motion, Rule 56(e) merely requires that Rule not rely solely on her pleadings. As the Supreme Court made clear in Celotex:

> . . . Rule 56(e) therefore requires the nonmoving party to go beyond the pleadings and by her own affidavits, or by the "depositions, answers to interrogatories, and admissions on file," designate "specific facts showing that there is a genuine issue for trial."
>
> We do not mean that the nonmoving party must produce evidence in a form that would be admissible at trial in order to avoid summary judgment. Obviously Rule 56 does not require the nonmoving party to depose her own witnesses. Rule 56(e) permits a proper summary judgment motion to be opposed by any of the kinds of evidentiary materials listed in Rule 56(c), except the mere pleadings themselves, and it is from this list that one would normally expect the nonmoving party to make the showing to which we have referred.

Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986) (quoting Fed. R. Civ. P. 56(e)).

Rule did go beyond her pleadings. She presented the testimony of Dr. Varia, who had testified on behalf of Heath at the medical review board hearing and stated in the following colloquy:

> Q. [In] the circumstances in this case[,] after they started the process of trying to place the interstitial needle and the ultrasonographer [Stoecker] requested that they remove the st[y]let and inject some saline in in order to see if he could better visualize it, was that a reasonable thing to do under the circumstances at that time?
>
> [Varia]: I think that that was a very good thought under the circumstances. There was a lot of difficulty with the placement of the catheter. That would help to visualize the catheter.

J.A. at 342. The district court entirely rejected this testimony of Varia, relying instead on Varia's newly filed affidavit on behalf of Best. See J.A. at 33. The majority ignores the fact that this testimony of Varia came on redirect examination, after the cross-examination to which the majority refers, and was specifically pointed at what Varia had just said during that cross-examination. See slip op. at 5. While Varia's credibility is certainly in question, as the nonmoving party Rule is entitled to the inference that the jury would believe Varia's first statement and not his second. See Ross v. Communications Satellite Corp., 759 F.2d 355, 364 (4th Cir. 1985).

The district court also rejected the various statements of Heath, Saul, and Stoecker to the effect that they were"surprised" when the catheter was severed by the obturator, as does the majority, see slip op. at 5, the district court labeling them as "conclusory," J.A. at 33. Moreover, the district court refused to accept the evidence at all, ruling that "when [Rule] questions the propriety of her physicians' actions herself, she certainly cannot come before this court and claim that those same doctors can testify regarding what reasonable consumers would expect the consequences of their actions to be." J.A. at 34 (emphasis in original). The majority uses nearly the same words.

See slip op. at 5. However, it is certainly not inconsistent for Rule to claim both that her physicians' misuse of the Flexineedle was negligent and that that misuse was reasonably foreseeable by Best. Furthermore, there certainly seems to be a genuine dispute as to a material issue created by Barnes's statement that"it is not unreasonable to expect any modern day physician who [has] ever started an IV to be familiar with th[e] risk [of shearing]" and the joint decision of three medical specialists--modern day physicians all--to withdraw the obturator and then reinsert it while the catheter remained within the body. Are we to believe that three totally unreasonable physicians just happened to be jointly performing a medical procedure on Rule? That three such specialists were "surprised" hardly seems conclusory but rather is probative of Rule's claim that their misuse of the device was reasonably foreseeable.

Finally, the district court ignored altogether in this context the report of Rule's biomedical device expert, W. Patrick McVay. Although his report did deal specifically with the issue of adequate warnings, his analysis found that

> [s]ince the failure of the product may have been associated with retracting and replacing the obturator while the needle is located within tissue, the "Flexi-Needle" product labeling contained no warning statement against withdrawing and reinserting the obturator once the needle penetrates skin or tissue. This type of misuse is inherent to the device since plastic materials are flexible, can kink and, therefore, be possibly torn or transected by the obturator tip if it should be replaced blindly.

J.A. at 42 (emphasis added).

Plainly, Rule opposed Best's motion for summary judgment with evidentiary material going beyond her pleadings. Taken together, the material amounts to the "specific facts" that three medical specialists, faced with the difficulty of visualizing the device via ultrasound, jointly embarked on a course that appeared to them at the time to be "a very good thought under the circumstances" but which nevertheless constituted a "misuse . . . inherent to the device." A de novo review thus plainly reveals that Rule has "set forth specific facts showing

there is a genuine issue for trial." Fed. R. Civ. P. 56(e). The district court therefore improperly granted Best summary judgment on the ground that Rule's physicians' misuse of the Flexineedle was not reasonably foreseeable. I believe this court should reverse the district court's order on her defect claim and remand for further proceedings.

B.

Rule's inadequate warnings claim is somewhat more problematic. As the district court properly noted, the plaintiff must show not only a breach of a duty to warn but also that the breach was a proximate cause of the injury. See J.A. at 35; see also Butler v. Navistar Int'l Transp. Corp., 809 F. Supp. 1202, 1208 (W.D. Va. 1991) (stating that even if there were a breach of a duty to warn, "plaintiff cannot recover unless she established this breach as the proximate cause" of the injury); Beale v. Jones, 171 S.E.2d 851, 853 (Va. 1970) (discussing nature of proximate cause). The district court ruled that because Rule's physicians never even read, let alone relied on, the warnings that were given by Best, this failure to read was a superseding cause that vitiates any negligence on Best's part. See J.A. at 35-36; see also Johnson v. Niagara Mach. & Tool Works, 666 F.2d 1223, 1225 (8th Cir. 1981) (stating that "an issue as to the adequacy of a warning necessarily presupposes that the operator has read the warning"). The majority agrees with this conclusion. See slip op. at 6.

Rule argues that her claim is not merely that Best failed to provide adequate warnings but that Best failed to provide adequate warnings that would reasonably be expected to reach the end-user physician. See Br. of Appellant at 23. To this end, Rule points to the following statement of her biomedical device expert McVay:

> It has been the practice in the medical device industry to print labeling requirements as stated above either on an insert included inside the primary package of each device or onto a package panel or label attached to the primary package. In the "Flexi-Needle" product it is conceivable to provide a "breather bag" with the information listed on the Tyvek side of the pouch so that this information was readily available for the user to read if he so chooses[,] or alternatively, an insert would be placed inside the pouch along with

> the product if the label copy was too long for the space available. If proper labeling was available, the physician would have had an opportunity to refresh his knowledge of the product before attempting to use the "Flexi-Needle" product.

J.A. at 42. The district court appears to ignore this statement and this aspect of Rule's claim altogether.

In this case it is necessary to balance Heath's testimony that he did not read any of the instructions or warnings that Best did provide,* see J.A. at 268, with the fact that the Flexineedle used here showed up in the operating room sterilized and ready for use sans all packaging. The question thus seems to be whether Best had a duty to provide its warnings on the side of a breather bag that a physician could examine in the operating room or whether a physician has an affirmative duty, prior to entering the operating room, to seek out instructions and warnings on the products he may use in the procedure. It is difficult to see how this issue could be resolved on Best's motion for summary judgment. The case relied upon by the district court to support its ruling that the failure to read was a superseding cause, Panousos v. Allen, 425 S.E.2d 496 (Va. 1993), in effect establishes the contrary. In Panousos, the Virginia Supreme Court rejected three arguments that a superseding cause instruction should have been given to the jury, differentiating between intervening and superseding causes as follows:

> There may, of course, be more than one proximate cause of an event. And not every intervening cause is a superseding cause. In order to relieve a defendant of liability for his negligence, negligence intervening between the defendant's negligence and the injury must so entirely supersede the operation of the defendant's negligence, that it alone,

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*The district court twice states that none of the three doctors had read the warnings Best provided. See J.A. at 35-36. However, I could only find in the record a statement from Heath that he had not read the warnings and nothing from Saul or Stoecker on the matter. Thus, there may still be a genuine issue as to whether Saul and Stoecker did read the warnings, a point which the majority ignores.

> without the defendant's [negligence contributing] thereto in the slightest degree, produces the injury.

Id. at 499 (internal quotation marks and citations omitted) (emphasis added). Because it cannot be said in this posture that Best's failure to provide adequate warnings that could reasonably have been expected to reach the physician did not in the slightest degree cause Rule's injury, the district court's determination that proximate cause could not be established as a matter of law is incorrect. A de novo review shows that there remains a genuine issue as to whether Best breached a duty to get its warnings to Rule's physicians, warnings which the district court already indicated presented a material question as to their adequacy, see J.A. at 35. I believe this court should thus reverse the district court's order on this claim and remand for further proceedings.

II.

Finally, there remains the district court's denial of Rule's motion to consolidate this action against Best with her action against her treating physicians. The majority does not reach this issue because of its disposition. See slip op. at 4 n.1. I believe that the district court's ruling on this issue should be reversed as well.

It is true that the district court possesses broad discretion as to whether to order consolidation under Rule 42(a). See A/S J. Ludwig Mowinckles Rederi v. Tidewater Constr. Corp., 559 F.2d 928, 933 (4th Cir. 1977). In this case, the district court stated only, "For the reasons given during the hearing on this motion, the court is of the opinion that consolidation is inappropriate." J.A. at 19. We, however, have no indication as to what those reasons were. As we have recently indicated, it is hard to review for abuse the exercise of a court's discretion when the reasons are nowhere apparent. See Steinke v. Beach Bungee, Inc., 105 F.3d 192, 197 (4th Cir. 1997).

Probative case law in this area is non-existent. Because I believe that the grant of summary judgment was improper as to both of Rule's claims, in these circumstances I think we should find it appropriate to consider either (1) vacating the order denying the consolidation motion and instructing the district court to provide reasons for its

decision or (2) reversing the lower court and instructing it to consolidate. And of these two possibilities, the latter is preferable in this instance. The facts of this case practically scream res ipsa loquitur. Whether the physicians were negligent in their use of the Flexineedle or Best provided a defective product or failed to adequately warn or both, clearly someone was at fault in Rule's injury. Unfortunately, it is too easy to imagine a jury in the Best case deciding it was the physicians' fault and a jury in the physicians' case deciding the blame should lie with the company. A single jury, however, could hardly fail to find fault somewhere or apportion fault among these defendants. Rule is surely correct that she is being put to a double burden in terms of costs, time, and efficiency or further delay in prosecuting the same basic facts simultaneously. See Reply Br. of Appellant at 7. This is a burden not of her making but purely one that is a quirk of Virginia's Medical Malpractice Act which forced her to file two separate actions to avoid the instant case being barred by the statute of limitations. Rule 42(a) contemplates consolidation precisely to avoid unnecessary costs or delay when actions involve common questions of law or fact. In these circumstances, I think Rule's actions should be consolidated: Let the physicians and Best fight out their liability in one trial.

III.

For the foregoing reasons, I believe that Rule has shown that genuine issues of material fact remain, that summary judgment was improvidently granted, and that Rule's case against Best should be consolidated with her case against the physicians. Because the majority has misapplied the burdens of a summary judgment motion and drawn the inferences in favor of the moving party, instead of the nonmoving party, I must dissent.